



OLYMPUS AMERICA INC.

Olympus America Inc. Response to the FDA and CDC Public Health Advisory
Infections from Endoscopes Inadequately Reprocessed by an
Automated Endoscope Reprocessing System

The safe use of Olympus flexible endoscopes in endoscopic procedures is of critical concern to Olympus. Accordingly, the reprocessing of endoscopes to render them patient-ready is a key element to the safe and appropriate use of endoscopes in a health care facility.

Endoscope reprocessing in an automated endoscope reprocessor (AER) has recently been the subject of a joint publication by FDA and CDC in a Public Health Advisory, published September 10, 1999, entitled *Infections from Endoscopes Inadequately Reprocessed by an Automated Endoscope Reprocessing System*. The Public Health Advisory was issued in order to alert the health care community to several incidents in which patients developed serious infections after being examined with bronchoscopes that apparently were inadequately reprocessed in an AER.

It is important to note that flexible endoscopes reprocessed in accordance with validated automated or manual reprocessing procedures are safe for use. The scientific literature indicates that documented instances of disease transmission during endoscopic procedures have been usually traced to breaches in the recommended endoscopic cleaning and disinfection procedures.

The FDA/CDC Public Health Advisory lists a number of recommendations regarding the safe use of any AER for endoscope reprocessing. One of the key recommendations is that the user confirm that a specific flexible endoscope model can be reprocessed in a particular AER. MediVators, Inc. has validated the use of the Olympus DSD Endoscope Disinfector by MediVators (also known as the MediVators Model DSD-91E) for automated high level disinfection of Olympus flexible endoscopes. A list of the specific Olympus flexible endoscope models which may be high level disinfected in the Olympus DSD is attached to this communication.

Another key recommendation of the FDA/CDC Advisory is that the user consider the incorporation of a final endoscope channel drying step into the endoscope reprocessing protocol. The Olympus DSD Endoscope Disinfector by MediVators may be programmed to dry endoscope channels with a final flush of alcohol and air to aid in the drying of the endoscope channels.

Olympus recommends that health care practitioners using AERs other than the Olympus DSD Endoscope Disinfector by MediVators contact the individual AER manufacturers to determine whether or not they have validated that a specific Olympus flexible endoscope model can be safely reprocessed in their equipment.

Finally, Olympus also recommends that health care practitioners and facilities follow established infection control guidelines established by professional organizations such as the American College of Gastroenterology (ACG), the American Gastroenterological Association (AGA), the American Society for Gastrointestinal Endoscopy (ASGE), the Society of Gastroenterology Nurses and Associates (SGNA), and the American Society for Testing and Materials (ASTM). Some of these national standards are available at no charge from Olympus America Inc. Please contact our Customer Call Center department at 1-800-848-9024 to request a copy of these standards.

**Olympus Flexible Endoscopes which may be High Level Disinfected
in the Olympus DSD Endoscope Disinfector by MediVators**

Gastrosopes		Duodenoscopes¹		Colonoscopes		Sigmoidoscopes
GIF-Q10	GIF-100	JF-10	JF-100	CF-10I	CF-100I	OSF-2
GIF-XQ10	GIF-1T100	JF-1T10		CF-10M	CF-100L	OSF-3
GIF-1T10	GIF-2T100	JF-V10	JF-130	CF-10L	CF-100HI	
GIF-2T10		TJF-10		CF-P10I	CF-100HL	CF-P10S
GIF-XP10	GIF-130	TJF-V10	TJF-130	CF-P10L	CF-100TL	CF-P20S
GIF-PV10	GIF-1T130			CF-V10I	CF-1T100	CF-V10S
GIF-XV10		JF-20		CF-V10L	CF-1T100I	CF-P20S
GIF-1TV10	GIF-Q140	JF-1T20		CF-1TV10L	CF-1T100L	CF-100S
GIF-V10	GIF-XQ140	TJF-20		CF-1T10I	CF-100TI	CF-130S
GIF-V10Z	GIF-1T140	TJF-M20		CF-1T10L		
GIF-XK10	GIF-P140					CF-140S
GIF-D10		TJF-30		CF-20I	CF-130I	
GIF-K10		JF-1T30		CF-20M	CF-130L	OSF-V60
				CF-20L		
GIF-Q20		PJF-7.5		CF-20HL	CF-140I	
GIF-XQ20				CF-20HI	CF-140L	
GIF-P20				CF-P20I	CF-Q140I	
GIF-XP20				CF-P20L	CF-Q140L	
GIF-PQ20				CF-1T20L		
GIF-XK20				CF-1T20I	CF-230I	
GIF-K20					CF-230L	
GIF-1T20				CF-UM20		
GIF-2T20					PCF-100	
				CF-30I		
GIF-Q30				CF-30M	PCF-130I	
GIF-XQ30				CF-30L	PCF-130L	
GIF-XT30						
GIF-P30				CF-40I	PCF-140I	
GIF-N30				CF-40L	PCF-140L	
GIF-1T30						
				PCF-10	PCF-230	
GIF-Q40				PCF-20		
GIF-XQ40						

Note:

1. Olympus DSD endoscope connectors to Olympus flexible duodenoscopes do not contain a branch to the duodenoscope elevator wire channel. The elevator wire channel must be manually reprocessed in accordance with the duodenoscope reprocessing instructions.

**Olympus Flexible Endoscopes which may be High Level Disinfected
in the Olympus DSD Endoscope Disinfector by MediVators**

<p>Enteroscopes SIF-10 SIF-20L SIF-100 SIF-SW</p>	<p>Ultrasound Endoscopes CF-UM20 JF-UM20 GF-UM20 GF-UC30P GF-UM30P GF-UMQ130 GF-UM130</p>	<p>Bronchoscopes BF-10 BF-200 BF-P10 BF-P200 BF-1T10 BF-1T200 BF-2T10 BF-3C10 BF-240 BF-6C10 BF-P240 BF-1T240 BF-6C240 BF-20 BF-20D BF-P20 BF-P20D BF-N20 BF-1T20 BF-1T20D BF-XT20 BF-3C20 BF-6C20 BF-30 BF-P30 BF-1T30 BF-Xt30 BF-3C30 BF-40 BF-P40 BF-1T40 BF-3C40 BF-XP40 BF-XT40</p>	<p>Cystoscopes CYF-2 CYF-3 CYF-200</p>
<p>Ureto-Renofiberscopes URF-P URF-P2</p>	<p>Hysteroscopes HYF-P HYF-1T</p>	<p>Laryngoscopes LF-DP LF-TP LF-1 LF-2</p>	<p>Choledochoscopes CHF-10 CHF-P10 CHF-B20 CHF-P20 CHF-P20Q CHF-XP20 CHF-T20 CHF-BP30</p>
<p>Rhinolaryngoscopes ENF-L3 ENF-P3 ENF-T3 ENF-1T10</p>	<p>Pancreatoscope PF-8P</p>		